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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,909	03/01/2001	Thomas William Rademacher	1012-102US	6839

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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,909	RADEMACHER ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/14/03*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *8-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 10/14/03.

The amendment filed 10/14/03 affects the application, 09/719,909 as follows:

1. Claims 1,4 and 8 have been amended. Claims 8-25 have been withdrawn. This leaves claims 1-7 for further examination. Claims 1-25 are pending in the application.
2. Applicant responds to the rejection under 35 USC 103 by amending claims 1,4 and 8.
3. The responsive to applicants' arguments is contained herein below.

Applicant's arguments with respect to claim 1-7 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pliml et al.(Clinical investigator, (1993 Oct) 71 (10) 770-3) in combination with STANLEY et al., (Cardiovascular Research, 1997, 33, 243-257 (AX: PTO/SB/O8A-B mailed July 13, 2001)) and RADEMACHER et al. (International Patent Publication WO 98/11435 to HOEFT RADEMACHER LIMTTED (N: PTO-892 mailed November 25, 2002)).

In claim 1, applicant claims "A composition comprising an inositolphosphoglycan (lPG) or an IPG synthetic analogue and ribose, wherein the IPG synthetic analogue has the ability to

activate pvruvate dehydrogenase phosphatase." Dependent claims 2 and 3 are drawn to specific IPG and IPG synthetic analogue. Dependent claims 5- 7 are drawn to various pharmaceutical formulations.

Pliml et al. disclose that ribose can be successfully used in the treatment of ischemic heart disease and muscular enzyme deficiencies (see abstract).

The difference between applicant's claimed composition and the composition of Pliml et al. is that Pliml et al. do not disclose the use of IPG or and IPG synthetic analogue in combination with ribose.

Stanley teaches that one of the proposed method of treating heart disease is by directly activating pyruvate dehydrogenase (PDH) (see page 249, right column, first full paragraph). Also, Stanley discloses that PDH is activated (stimulated) by a specific PDH phosphatase (see page 245, right column, first full paragragh). In general, STANLEY teaches that metabolic therapies for the treatment of heart disease have focused on (1) increasing myocardial glycolysis by increasing glucose uptake during ischaemia or by increasing glycogen levels prior to a surgical procedure; (2) inhibiting myocardial fatty acid oxidation, thus increasing carbohydrate oxidation and flux through pyruvate dehydrogenase (PDH); or (3) activating PDH (for example by stimulating PDH phosphatase) and increasing carbohydrate oxidation. Finally, STANLEY teaches on page 253, in the Summary and Conclusions, that metabolic interventions aimed at enhancing glucose utilization and pyruvate oxidation at the expense of fatty acid oxidation is a valid therapeutic approach to the treatment of myocardial ischaemia.

RADEMACHER et al. disclose that IPG P-type activates pyruvate dehydrogenase

phosphatase, and can be employed as a therapeutic agent for the treatment of diabetes (see page 2, lines 26-34). Thus, Stanley and Rademacher et al. aforementioned disclosure implies that compounds such as IPG P-type compounds via pyruvate dehydrogenase phosphatase activation, can activate PDH (since pyruvate dehydrogenase phosphatase can activate) and thus, can be used to treat heart disease.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared a composition of Pliml et al. in view of Rademacher et al. and Stanley comprising of ribose and IPG or IPG synthetic analogue, to treat heart disease such as ischaemia heart disease, since Stanley discloses that heart disease can be treated by directly activating pyruvate dehydrogenase (PDH) (which in turn can be stimulated by pyruvate dehydrogenase phosphatase) and RADEMACHER et al. disclose that IPG P-type activates pyruvate dehydrogenase phosphatase (PDH phosphatase), and the combination of compounds that are used to treat the same diseases are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated to have prepared a compound or composition of Pliml et al. in view of Rademacher et al. and Stanley comprising of ribose and IPG or IPG synthetic analogue, to treat heart disease such as ischaemia heart disease, since Stanley discloses that heart disease can be treated by directly activating pyruvate dehydrogenase (PDH) (which in turn can be stimulated by pyruvate dehydrogenase phosphatase) and RADEMACHER et al. disclose that IPG P-type activates pyruvate dehydrogenase phosphatase (PDH phosphatase)), and the combination of compounds that are used to treat the

same diseases are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pliml et al. and Stanley et al. as applied to claim 1 above, and further in view of Mentzer, Jr et al.(US 4,880,783).

Claim 4 is drawn to composition of claim 1, further comprising adenosine or purine or a precursor of adenine nucleotide synthesis.

Mentzer, Jr et al. disclose a solution comprising adenosine and ribose that is used to treat or reduce ischemic damage of the heart (see abstract).

The difference between applicant's claimed composition and the composition taught by Pliml et al. and Stanley et al., is that the applicant also uses adenosine in his composition in addition to ribose and IPG or IPG synthetic analogue. However, Mentzer, Jr et al. disclose that adenosine together with ribose can be used to treat or reduce ischemic damage of the heart (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Pliml et al., Stanley et al. and Mentzer, Jr et al., to prepare a composition comprising a combination of ribose, IPG or IPG synthetic analogue and adenosine. to treat heart disease such as ischaemia heart disease, since the combination of compounds that are used to treat the same diseases or condition is well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new

composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Pliml et al., Stanley et al. and Mentzer, Jr et al., to prepare a composition comprising a combination of ribose, IPG or IPG synthetic analogue and adenosine to treat heart disease such as ischaemia heart disease, since the combination of compounds that are used to treat the same diseases or condition is well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

April 16, 2004.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600